



September 2, 2021

Via E-File

The Honorable Leonard P. Stark  
J. Caleb Boggs Federal Building  
844 N. King Street, Unit 26  
Room 6124  
Wilmington, DE 19801-3555

**FILED UNDER SEAL**

**Re: Natera, Inc. v. ArcherDX, LLC, et al., C.A. No. 20-cv-125-LPS**

Dear Judge Stark:

Defendants Invitae Corporation and ArcherDX, LLC (together, “Defendants”) respectfully seek leave to amend their Answer and Counterclaims (D.I. 133) to add an inequitable conduct defense and corresponding declaratory judgment counterclaims. Defendants’ proposed amended pleading and a redline illustrating the changes are submitted herewith. *See* Exs. A–B. Defendants attempted to obtain Natera’s consent for the amendment, but Natera refused.

**A. Factual Background**

Defendants’ inequitable conduct defense stems from filings that Natera made in the Patent Office just two months ago on June 24 and June 25. On these dates, Natera filed Petitions with the Patent Office to dramatically change inventorship on four of the five patents-in-suit, including U.S. Patent Nos. 10,538,814 (“the ’814 patent”), 10,590,482 (“the ’482 patent”), 10,557,172 (“the ’172 patent”), and 10,731,220 (“the ’220 patent”). For three of the patents, Natera sought to add Johan Baner, Milena Banjevic, Allison Ryan, and Zachary Demko as inventors and remove Joshua Babiarz, Tudor Constantin, Lane Eubank, Huseyin Kirkizlar, and Onur Sakarya as inventors. It is difficult to believe that Natera could have been so grossly mistaken in its original inventorship designation that it needed to make a change involving *nine* different individuals nearly a year and a half after initiating litigation.

In fact, it is easy to understand why Natera now attempts these changes. It turns out that several of the inventors that Natera originally listed on its patents (including Joshua Babiarz, Tudor Constantin, Lane Eubank, Huseyin Kirkizlar, and Onur Sakarya) did not even work at Natera until long *after* the appearance of key prior art that Defendants have identified in this case. Natera’s change of inventorship was done with deceptive intent to name on the patents a false inventorship group consisting solely of individuals who worked at Natera in a time frame consistent with the alleged October 2011 invention date upon which Natera now wishes to rely to avoid such prior art. By removing as inventors several individuals that were not even affiliated with Natera until long after Natera’s desired invention date and adding individuals who were, Natera seeks to avoid any inference that its alleged invention post-dates the prior art relied upon in this case by Defendants.

Natera’s deceptive intent is amply supported by the record of several depositions that Defendants have taken since Natera changed its inventorship group, as reflected at length in Defendants’ proposed amended pleading. [REDACTED]

[REDACTED]

All of the foregoing facts, and many more, are plead in Defendants' proposed amended complaint.

The evidence cited in the proposed amended pleading further shows there is little reason to believe Natera identified an erroneous inventorship group when it originally filed the patents.

[REDACTED]

Rather, Natera's motive was simply to remove inventors that would jeopardize its ability to improperly claim the benefit of an earlier alleged invention date. Indeed, as Defendants allege in their pleading, Natera failed to submit to the Patent Office Defendants' invalidity contentions and failed to notify the Patent Office of the serious questions regarding Natera's priority claim and invention date that have been raised in the instant litigation.

Pursuant to the Scheduling Order, motions to amend the pleadings must have been filed on or before December 1, 2020. *See* D.I. 60. The conduct underlying the proposed amendment of defense of inequitable conduct and four counterclaims seeking declaratory judgment of unenforceability due to inequitable conduct did not occur until at least in and around June 2021, after the filing deadline. Defendants have good cause to amend the complaint at this stage of the litigation. Natera has not identified any substantive opposition to the amended pleading and, indeed, there is none. As discussed below, allowing Defendants to amend its answer and counterclaims is not only proper, but necessary in light of Natera's conduct. Defendants respectfully request this Court permit the filing of the First Amended Answer and Counterclaims, attached as Exhibit A.

#### **B. Leave To Amend A Complaint Should Be Freely Granted**

Pursuant to Federal Rule of Civil Procedure 15(a)(2), a party may amend its pleading "only with the opposing party's written consent or the court's leave," and the "court should freely give leave when justice so requires." The decision to grant or deny leave to amend lies within the discretion of the court. *See Foman v. Davis*, 371 U.S. 178, 182 (1962); *In re Burlington Coat Factory Secs. Litig.*, 114 F.3d

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<sup>1</sup> [REDACTED]

1410, 1434 (3d Cir. 1997). The Third Circuit has adopted a liberal approach to pleading amendments. *See Dole v. Arco Chem. Co.*, 921 F.2d 484, 486-87 (3d Cir. 1990). In the absence of undue delay, bad faith, repeated failure to cure deficiencies by previous amendment, or dilatory motives on the part of the moving party, amendment should be freely granted, unless it would be futile or unfairly prejudicial to the non-moving party. *See Foman*, 371 U.S. at 182; *In re Burlington*, 114 F.3d at 1434. Each factor favors permitting Defendants to amend at this early stage.

**C. The Motion Is Not Unduly Delayed Or Prejudicial, And Is Made in Good Faith**

Natera cannot credibly contend that Defendants' motion to amend is delayed, prejudicial, or not in good faith. Defendants' inequitable conduct defense stems from Natera's June 24 and June 25 Patent Office filings and discovery that was gleaned from depositions taken as soon as practicably possible after Natera's Patent Office filings. *See ICU Medical, Inc. v. RyMed Technologies, Inc.*, 674 F. Supp. 2d 574, 576 (D. Del. 2009) (finding good cause when defendant's motion to amend after pleading deadline was based on a new set of facts obtained during discovery). Only two months passed from the time of the first facts that gave rise to Defendants' defense on June 24 and June 25 and the filing of this motion. When one takes into consideration that inequitable conduct pleadings must satisfy the enhanced Rule 9(b) standard, there can be no dispute that Defendants acted diligently. Moreover, since the amendment was sought without undue delay, it is not unduly prejudicial to Natera. *Id.* at 578-79. Natera cannot possibly cry prejudice because it waited a year and a half into the case to make wholesale changes to its inventorship group. Had Natera wished to avoid any alleged prejudice from its Patent Office filings, it easily could have submitted its Petitions to correct inventorship far earlier. Finally, this motion is made in good faith; Defendants' amended answer is necessary only in response to Natera's belated conduct regarding inventorship of the '482, '814, '172, and '220 patents. The evidence cited in the complaint overwhelmingly establishes the merits of Defendants' inequitable conduct defense, and thus proves good faith.

**D. The Amendments Are Not Futile**

An amendment is futile only if it would not survive a motion to dismiss for failure to state a claim upon which relief could be granted. *See Alvitt v. Suzuki*, 227 F.3d 107, 121 (3d Cir. 2000). The amended answer here, however, includes detailed facts and allegations gleaned from at least 10 depositions substantiating inequitable conduct by Natera by its attempt to change inventorship. Because it is a "critical requirement for obtaining a patent, inventorship is material." *PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315, 1321 (Fed. Cir. 2000). The proposed amendments thus cannot be deemed futile.

For the foregoing reasons, Defendants respectfully request leave to amend their answer and counterclaims to include a defense of inequitable conduct and corresponding counterclaims.

Respectfully submitted,

/s/ Brian E. Farnan

Brian E. Farnan

cc: Counsel of Record (via E-Mail)